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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/734,606 | 12/11/2003 | Bei Chen | ABGENIX.058A | 9342 |

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| EXAMINER | |
|---|---|
| KIM, YUNSOO | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/734,606 | CHEN ET AL. | |
| | Examiner | Art Unit | |
| | Yunsoo Kim | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/2/04,2/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-39 are pending.

2. Applicants' election with traverse of Group I, drawn to claims 1-9 and 25-39, with the elected species of mannitol in the reply filed on 6/17/05 is acknowledged.

Applicants' traversal is based on that the antibody composition of claim cannot be formulated other than the process recited in claim 10, the lyophilization. However, spray – drying or air-drying method is well known in the art to formulate solid composition. As the antibody formulation of claim 1 can be achieved by the materially different method not recited in Group II, they are patentably distinct.

Applicants further traverse based on search burden of Groups I and II does not go beyond the search burden of Group I. As referred in the original restriction, these groups are distinct and have acquired a separate status in the art as shown by their different classification. They require non-co-extensive searches. Furthermore, the art reads on mannitol would be different from the art teaches arginine.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-24 are withdrawn from further consideration by the examiner, 37 C.F.R.§ 1.142(b) as being drawn to a nonelected invention.

Claims 1-9 and 25-39 read on elected species of mannitol are under consideration in the instant application.

3. Applicants' IDS filed on 7/2/04 and 2/4/05 are acknowledged. The international search report has been crossed out.

4. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 28 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Andya et al (WO 97/04801).

The '801 publication teaches stable lyophilzed anti-HER2 antibody (i.e. human monoclonal IgG) formulation comprising 1-20 mM histidine buffer, 38mM mannitol and 20mM sucrose (i.e. excipient) (Fig. 4, p. 4, Fig. 4 description, p. 15, lines 2-6, claims 20-23, p. 20, Table 2, p. 23, Table 3, p. 25, Table 5-6, p.7-8).

The '801 publication further teaches stable aqueous anti-HER2 antibody formulation comprising 1-20mM histidine buffer, 38mM mannitol and 20mM sucrose and a kit comprising said antibody formulation (Fig 7, Fig.7 description, p. 15, lines 2-6, p. 18, lines 16-33, claims 1-5, claims 14-15)

As recognized in p. 8, [0037] of the specification of the instant application, human antibody is produced by replacing of "most" of human antibody producing genes, the referenced humanized antibody, anti-HER2 meets the claimed limitation. Thus, prior art teachings anticipate the claimed invention.

7. Claims 1-3, 5, 6, 8, 9, 25-27, 29-33, 35, 36, 28 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Andya et al (U.S. Pat. No. 6,685,940 B2).

The '940 patent teaches stable lyophilzed anti-HER2 antibody (i.e. human monoclonal IgG) formulation comprising 1-20 mM histidine buffer, 38mM mannitol and 20mM sucrose (i.e. excipient) (Fig. 4, col. 4, Fig. 4 description, col. 15, lines 41-50, col. 16, lines 10-35, claims 1-4, col. 21-22, Table 2).

The '940 publication further teaches stable aqueous anti-HER2 antibody formulation comprising 1-20mM histidine buffer, 38mM mannitol and 20mM sucrose and a kit comprising said antibody formulation (Fig 7, Fig.7 description, col. 19, under article of manufacture, col. 26, Tables 4-5, claims 8-12 and 15-16).

As recognized in p. 8, [0037] of the specification of the instant application, human antibody is produced by replacing of "most" of human antibody producing genes, the referenced humanized antibody (col. 12), anti-HER2 meets the claimed limitation. Thus, prior art teachings anticipate the claimed invention.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 7, 25, 28, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/04801 or U.S. Pat. No. 6,685,940 in view of Yang et al. (Cancer Research, 1999, 59:1236-1243).

The '801 publication and the '940 patent have been discussed, supra.

The '801 publication and the '940 patent do not teach fully human IgG2 monoclonal antibody.

However, Yang et al. teach fully human IgG2 monoclonal antibody to the human epidermal growth factor (EGF) receptor (abstract, p. 1237, col. 2, result)

Therefore, one of the ordinary skill in the art would have been motivated to combine fully human IgG2 monoclonal antibody as taught Yang et al., to prolong stability of formulation upon storage and delivery ('940 patent, col. 1, liens 55-61)

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 1, 4, 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/04801 or U.S. Pat. No. 6,685,940 in view of U.S. Pat. No. 5,252,480.

The '801 publication and the '940 patent have been discussed, supra.

The '801 publication and the '940 patent do not teach arginine as an excipient.

However, the '480 patent teaches arginine has been used in antibody purification to prevent agglutination which leads to depression of antibody activity (col. 8, lines 36-54).

Therefore, one of the ordinary skill in the art would have been motivated to combine arginine as taught the '480 patent to prevent agglutination of antibody in the antibody composition taught by the '801 publication and the '940 patent.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 1, 2005

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